DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Chlortetracycline Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pennfield Oil Co. The supplemental NADA provides for a revised withdrawal time for use of chlortetracycline (CTC) powder in swine drinking water.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, is sponsor of NADA 65–480 that provides for use of CTC hydrochloride soluble powder for making medicated drinking water for swine and cattle for treatment and control of bacterial enteritis and bacterial pneumonia. The firm filed a supplemental NADA that provides for a zero-day slaughter withdrawal period after use of the product for treatment and control of disease in swine. The supplemental NADA is approved as of December 22, 1999, and 21 CFR 520.445b(d)(1)(i)(A)(2) is amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.445b [Amended]

2. Section 520.445b *Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate)* is amended in paragraph (d)(1)(i)(A)(2) by removing the phrase ''do not slaughter animals for food within 5 days of treatment''.

Dated: 1/28/2000
January 28, 2000

Claire M. Lathers

Claire M. Lathers
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

BILLING CODE 4160–01–F

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